Mark P. Robinson, Jr., Esq.
mrobinson@rcrlaw.net
ROBINSON, CALCAGNIE & ROBINSON INC.
620 Newport Center Drive, 7th Floor
Newport Beach CA 92660
Telephone: (949) 720-1288
Facsimile: (949) 720-1292

Attorneys for Plaintiffs

FILED
08 FEB 21 PM 4:12
CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
CP
BY: DEPUTY

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SAN DIEGO DIVISION

MARILYN BENNETT, SCOTT BENNETT, and CHAD BENNETT, all individually and as successors in interest to the Estate of ALAN BENNETT, Deceased, Plaintiffs, vs. PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC, Defendants.	CASE NO. '08 CV 0341 LAB ~~LSP~~ POR **COMPLAINT** Jury Trial Demanded

Plaintiffs, by and through the undersigned attorneys of record, and for the Complaint against defendants, PFIZER, INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC, states and alleges as follows:

PRELIMINARY STATEMENT

1. Plaintiffs, MARILYN BENNETT, SCOTT BENNETT and CHAD BENNETT, are the sole legal successors in interest to the estate of the decedent and succeed to the decedent's causes of action because there is no personal representative of the Estate of ALAN BENNETT.

CR

Plaintiff, MARILYN BENNETT, the wife of the decedent, and plaintiffs, SCOTT BENNETT and CHAD BENNETT, the sons of the decedent, have filed the declaration under penalty of perjury required by Code of Civil Procedure section 377.32. Plaintiffs bring this action as the successors in interest to the decedent as well as individually under the laws of the State of California, pursuant to Cal. Code Civ. Proc. §§ 377.10 et seq., to recover damages for personal injuries sustained by, and the wrongful death of, plaintiffs' decedent as the direct and proximate result of defendants' wrongful conduct in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the prescription drug Neurontin, especially for such "off-label" use as the treatment of pain, a purpose for which Neurontin had not received FDA approval, and at dosages higher than had been approved by the FDA and had been properly tested on humans, even though the drug had not been tested and studied for that purpose and had not been found to be safe and effective at any dosage for the treatment of pain.

JURISDICTION AND VENUE

2. Jurisdiction exists as against defendants, PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC (hereinafter "PARKE-DAVIS"), WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC, pursuant to:

(a) 28 U.S.C. Section 1332, in that plaintiffs are successors in interest to the Estate of ALAN BENNETT, Deceased, plaintiff, MARILYN BENNETT, is a citizen and resident of the State of California, plaintiffs, SCOTT BENNETT and CHAD BENNETT, are citizens and residents of the State of Colorado, at the time of his death, plaintiffs' decedent, ALAN BENNETT, was a citizen and resident of the State of California, defendant, PFIZER INC., is incorporated in business in the State of Delaware, and maintains its principal place of business in the State of New York, defendant, PARKE-DAVIS, is incorporated in the State of Michigan, and maintains its principal place of business in the State of New Jersey, defendant, WARNER-LAMBERT COMPANY, is incorporated in the State of Delaware and maintains its principal place of business in the State of New Jersey, defendant, WARNER-LAMBERT COMPANY

LLC, is a limited liability company organized under the laws of the State of Delaware, whose sole shareholder and member is defendant, PFIZER INC., and because the amount in controversy exceeds the sum of $75,000.00, and because there is complete diversity of citizenship between plaintiffs and defendants.

(b) Venue properly lies in this Court pursuant to 28 U.S.C. Section 1391(a)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

PARTIES

3. That the above-named plaintiffs' decedent, ALAN BENNETT, was the Husband, Father and Next of Kin of the plaintiffs above-named, MARILYN BENNETT, SCOTT BENNETT and CHAD BENNETT, and on and prior to the 2nd day of May, 2001, plaintiffs' decedent and plaintiff, MARILYN BENNETT, resided in San Diego County, State of California, and plaintiffs, SCOTT BENNETT and CHAD BENNETT, resided in Arvada, Colorado.

4. That at the time of death on May 2, 2001, plaintiffs' decedent was then of the age of 48 years and prior thereto, was generally in good health, industrious and possessed all faculties.

5. That at the time of plaintiffs' decedent's death, he was survived by his wife, plaintiff, MARILYN BENNETT, of Vista, California, and his sons, plaintiffs, SCOTT BENNETT and CHAD BENNETT, of Arvada, Colorado.

6. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., was and still is a foreign corporation organized under the laws of the State of Delaware.

7. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., was and still is a foreign corporation authorized to do business in the State of California.

8. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., was and still is a business entity actually doing business in the State of California.

9. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC (hereinafter "PARKE-DAVIS"), was and still is a foreign corporation organized under the laws of the State of Michigan.

10. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, was and still is a foreign corporation authorized to do business in the State of California.

11. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, was and still is a business entity actually doing business in the State of California.

12. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY was and still is a foreign corporation organized under the laws of the State of Delaware.

13. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, was and still is a foreign corporation authorized to do business in the State of California.

14. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, was and still is a business entity actually doing business in the State of California.

15. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, is a division of defendant, WARNER-LAMBERT COMPANY.

16. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, is a subsidiary of defendant, WARNER-LAMBERT COMPANY.

17. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, was and still is a foreign limited liability company organized under the laws of the State of Delaware.

18. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, was and still is a foreign limited liability company

authorized to do business in the State of California.

19. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, was and still is a business entity actually doing business in the State of California.

20. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., is the sole shareholder and member of defendant, WARNER-LAMBERT COMPANY LLC.

21. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, is a division of defendant, WARNER-LAMBERT COMPANY LLC.

22. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, is a subsidiary of defendant, WARNER-LAMBERT COMPANY LLC.

23. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, is a division of defendant, PFIZER INC.

24. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, is a subsidiary of defendant, PFIZER INC.

25. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, is a successor in interest to defendant, PARKE-DAVIS.

26. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, is a division of defendant, PFIZER INC.

27. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, is a subsidiary of defendant, PFIZER INC.

28. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, is a successor in interest to defendant, PARKE-DAVIS.

29. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, is a successor in interest to defendant, PARKE-DAVIS.

30. That on a date prior to May 2, 2001, defendant, WARNER-LAMBERT COMPANY, assumed the assets and liabilities of defendant, PARKE-DAVIS.

31. That on a date prior to May 2, 2001, defendant, WARNER-LAMBERT COMPANY, expressly assumed all liabilities and obligations of defendant, PARKE-DAVIS.

32. That on a date prior to May 2, 2001, defendant, WARNER-LAMBERT COMPANY, impliedly assumed all liabilities and obligations of defendant, PARKE-DAVIS.

33. That on a date prior to May 2, 2001, defendant, PARKE-DAVIS, and defendant, WARNER-LAMBERT COMPANY, merged with each other.

34. That on a date prior to May 2, 2001, defendant, PARKE-DAVIS, merged with defendant, WARNER-LAMBERT COMPANY, and defendant, PARKE-DAVIS, became a part of defendant, WARNER-LAMBERT COMPANY.

35. That on a date prior to May 2, 2001, defendant, PARKE-DAVIS, and defendant, WARNER-LAMBERT COMPANY, consolidated with each other.

36. That on or about December 31, 2002, defendant, WARNER-LAMBERT COMPANY LLC, assumed the assets and liabilities of defendant, PARKE-DAVIS.

37. That on or about December 31, 2002, defendant, WARNER-LAMBERT COMPANY LLC, expressly assumed all liabilities and obligations of defendant, PARKE-DAVIS.

38. That on or about December 31, 2002, defendant, WARNER-LAMBERT COMPANY LLC, impliedly assumed all liabilities and obligations of defendant, PARKE-DAVIS.

39. That on or about December 31, 2002, defendant, PARKE-DAVIS, and defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

40. That on or about December 31, 2002, defendant, PARKE-DAVIS, merged with defendant, WARNER-LAMBERT COMPANY LLC, and defendant, PARKE-DAVIS, became a part of defendant, WARNER-LAMBERT COMPANY LLC.

41. That on or prior to December 31, 2002, defendant, PARKE-DAVIS, and defendant, WARNER-LAMBERT COMPANY LLC, consolidated with each other.

42. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, is a successor in interest to defendant, WARNER-

LAMBERT COMPANY.

43. That on or prior to December 31, 2002, defendant, WARNER-LAMBERT COMPANY LLC, assumed the assets and liabilities of defendant, WARNER-LAMBERT COMPANY.

44. That on or prior to December 31, 2002, defendant, WARNER-LAMBERT COMPANY LLC, expressly assumed all liabilities and obligations of defendant, WARNER-LAMBERT COMPANY.

45. That on or prior to December 31, 2002, defendant, WARNER-LAMBERT COMPANY LLC, impliedly assumed all liabilities and obligations of defendant, WARNER-LAMBERT COMPANY.

46. That on or prior to December 31, 2002, defendant, WARNER-LAMBERT COMPANY, and defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

47. That on or prior to December 31, 2002, defendant, WARNER-LAMBERT COMPANY, merged with defendant, WARNER-LAMBERT COMPANY LLC, and defendant, WARNER-LAMBERT COMPANY, became a part of defendant, WARNER-LAMBERT COMPANY LLC.

48. That on or prior to December 31, 2002, defendant, WARNER-LAMBERT COMPANY, and defendant, WARNER-LAMBERT COMPANY LLC, consolidated with each other.

49. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., is a successor in interest to defendant, PARKE-DAVIS.

50. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., is a successor in interest to defendant, WARNER-LAMBERT COMPANY.

51. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., is a successor in interest to defendant, WARNER-LAMBERT COMPANY LLC.

52. That on a date prior to May 2, 2001, defendant, PFIZER INC., assumed the assets and liabilities of defendant, PARKE-DAVIS.

53. That on a date prior to May 2, 2001, defendant, PFIZER INC., assumed the assets

and liabilities of defendant, WARNER-LAMBERT COMPANY.

54. That on a date prior to May 2, 2001, defendant, PFIZER INC., expressly assumed all liabilities and obligations of defendant, PARKE-DAVIS.

55. That on a date prior to May 2, 2001, defendant, PFIZER INC., impliedly assumed all liabilities and obligations of defendant, PARKE-DAVIS.

56. That on a date prior to May 2, 2001, defendant, PFIZER INC., expressly assumed all liabilities and obligations of defendant, WARNER-LAMBERT COMPANY.

57. That on a date prior to May 2, 2001, defendant, PFIZER INC., impliedly assumed all liabilities and obligations of defendant, WARNER-LAMBERT COMPANY.

58. That on or prior to December 31, 2002, defendant, PFIZER INC., assumed the assets and liabilities of defendant, WARNER-LAMBERT COMPANY LLC.

59. That on or prior to December 31, 2002, defendant, PFIZER INC., expressly assumed all liabilities and obligations of defendant, WARNER-LAMBERT COMPANY LLC.

60. That on or prior to December 31, 2002, defendant, PFIZER INC., impliedly assumed all liabilities and obligations of defendant WARNER-LAMBERT COMPANY LLC.

61. That on a date prior to May 2, 2001, defendant, PFIZER INC., and defendant, PARKE-DAVIS, merged with each other.

62. That on a date prior to May 2, 2001, defendant, PFIZER INC., and defendant, WARNER-LAMBERT COMPANY, merged with each other.

63. That on or before May 2, 2001, defendant, PFIZER INC., and defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

64. That on a date prior to May 2, 2001, defendant, PFIZER INC., and defendant, PARKE-DAVIS, merged with each other and defendant, PARKE-DAVIS, became a part of defendant, PFIZER INC.

65. That on a date prior to May 2, 2001, defendant, PFIZER INC., and defendant, WARNER-LAMBERT COMPANY, merged with each other and defendant, WARNER-LAMBERT COMPANY, became a part of defendant, PFIZER INC.

66. That on or prior to December 31, 2002, defendant, PFIZER INC., and defendant,

WARNER-LAMBERT COMPANY LLC, merged with each other and defendant, WARNER-LAMBERT COMPANY LLC, became a part of defendant, PFIZER INC.

67. That on a date prior to May 2, 2001, defendant, PFIZER INC., and defendant, PARKE-DAVIS, consolidated with each other.

68. That on a date prior to May 2, 2001, defendant, PFIZER INC., and defendant, WARNER-LAMBERT COMPANY, consolidated with each other.

69. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., has its principal place of business in the State of New York.

70. In the year 2000, defendant, PFIZER INC., acquired defendant, WARNER-LAMBERT COMPANY, and as the result of that acquisition, defendant, PFIZER INC., is responsible for all liabilities resulting from the acts or omissions of defendant, WARNER-LAMBERT COMPANY, which occurred prior to such acquisition.

71. In the year 2000, defendant, PFIZER INC., acquired defendant, PARKE-DAVIS, a division of Warner-Lambert Company, and as the result of that acquisition, defendant, PFIZER INC., is responsible for all liabilities resulting from the acts or omissions of defendant, PARKE-DAVIS, which occurred prior to such acquisition.

72. On or prior to December 31, 2002, defendant, PFIZER INC., acquired defendant, WARNER-LAMBERT COMPANY LLC, and pursuant to the terms of and conditions of that acquisition, defendant, PFIZER INC., is responsible for all acts or omissions of defendant, WARNER LAMBERT-COMPANY, LLC, occurring prior to such acquisition.

73. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., presently markets and sells the drug Neurontin.

74. That on a date prior to May 2, 2001, defendant, PFIZER INC., marketed and sold the drug Neurontin.

75. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of California and contracts to provide goods and services in the

State of California.

76. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., committed a tortious act inside the State of California, which caused injury to plaintiffs' decedent inside the State of California.

77. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., committed a tortious act outside the State of California, which caused injury to plaintiffs' decedent inside the State of California.

78. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., regularly does and solicits business and engages in a persistent course of conduct in the State of California, deriving substantial revenue from goods and products consumed in the State of California.

79. That at all times hereinafter mentioned, upon information and belief, defendant, PFIZER INC., expects or should reasonably expect its acts to have consequences in the State of California, and derives substantial revenue from interstate or international commerce.

80. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, presently markets and sells the drug Neurontin.

81. That on a date prior to May 2, 2001, defendant, PARKE-DAVIS, marketed and sold the drug Neurontin.

82. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of California and contracts to provide goods and services in the State of California.

83. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, committed a tortious act inside the State of California, which caused injury to plaintiffs' decedent inside the State of California.

84. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, committed a tortious act outside the State of California, which caused injury to

plaintiffs' decedent inside the State of California.

85. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, regularly does and solicits business and engages in a persistent course of conduct in the State of California, deriving substantial revenue from goods and products consumed in the State of California.

86. That at all times hereinafter mentioned, upon information and belief, defendant, PARKE-DAVIS, expects or should reasonably expect its acts to have consequences in the State of California, and derives substantial revenue from interstate or international commerce.

87. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, presently markets and sells the drug Neurontin.

88. That on a date prior to May 2, 2001, defendant, WARNER-LAMBERT COMPANY, marketed and sold the drug Neurontin.

89. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of California and contracts to provide goods and services in the State of California.

90. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, committed a tortious act inside the State of California, which caused injury to plaintiffs' decedent in the State of California.

91. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, committed a tortious act outside the State of California, which caused injury to plaintiffs' decedent inside the State of California.

92. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY, regularly does and solicits business and engages in a persistent course of conduct in the State of California, deriving substantial revenue from goods and products consumed in State of California.

93. That at all times hereinafter mentioned, upon information and belief, defendant,

WARNER-LAMBERT COMPANY, expects or should reasonably expect its acts to have consequences in the State of California, and derives substantial revenue from interstate or international commerce.

94. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, presently markets and sells the drug Neurontin.

95. That on a date prior to May 2, 2001, defendant, WARNER-LAMBERT COMPANY LLC, marketed and sold the drug Neurontin.

96. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of California.

97. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, committed a tortious act inside the State of California, which caused injury to plaintiffs' decedent inside the State of California.

98. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, committed a tortious act outside the State of California, which caused injury to plaintiffs' decedent inside the State of California.

99. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, regularly does and solicits business and engages in a persistent course of conduct in the State of California, deriving substantial revenue from good and products consumed in the State of California.

100. That at all times hereinafter mentioned, upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, regularly does and solicits business and engages in a persistent course of conduct in the State of California, deriving substantial revenue from interstate commerce.

BACKGROUND

STATEMENT OF THE CASE

101. Pursuant to the Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. §§ 301 et seq.,

new pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a) and (d).

102. However, the FDCA does not prevent doctors from prescribing a drug approved for a particular use for other uses that are different than those approved by the FDA ("off-label" usage).

103. Nonetheless, even though physicians may prescribe drugs for "off-label" usage, the FDCA prohibits drug manufacturers themselves from marketing and promoting a drug for a use that the FDA has not approved. 21 U.S.C. § 331(d).

104. A manufacturer illegally "misbrands" a drug if the drug's labeling includes information about unapproved uses or if the manufacturer engages directly or indirectly in marketing or promoting the drug for unapproved uses.

105. Instead, if a manufacturer desires to market and promote the drug for new use s in addition to those already approved, the materials on "off-label" usage must meet certain stringent requirements and the manufacturer must resubmit the drug to the FDA testing and approval process for the proposed new use.

106. The above-described statutory and regulatory system and process is designed to protect the public, including plaintiff, from the dangers arising from drugs which, although approved for a certain specific condition, disease or purpose, could cause injury and harm if used for an "off-label" purpose without adequate study and testing of the drug for such "off-label" usage, and to protect the public, including plaintiffs' decedent herein, from the dangers arising from deceptive, misleading, and inaccurate advertising, marketing, and promotional materials issued directly or indirectly by the manufacturer to encourage the "off-label" usage of the drug without adequate testing and study of that drug for such "off-label" usage.

107. PARKE-DAVIS, now owned by PFIZER INC., applied for, and in December, 1993, received FDA approval to market and sell Neurontin solely for "adjunctive therapy" in the treatment of certain types of seizures in adult patients suffering from epilepsy, and the FDA approved labeling of Neurontin for that purpose and stated that the drug is only effective at 900 to

1800 milligrams per day.

108. At no time prior to plaintiffs' decedent being prescribed Neurontin, did defendants receive FDA approval for any other use of Neurontin except for the above-described treatment of epilepsy or for higher dosages for any purpose, and the FDA never approved the usage of Neurontin at any dosage for the treatment of pain.

109. Commencing in 1995, defendants, as the manufacturer of Neurontin, began to directly and indirectly advertise, market and promote Neurontin for additional "off-label" uses for which FDA approval had not been obtained, including treatment for pain and at higher dosages than had been tested and approved, in violation of the above-described statutory and regulatory system and process, including the FDCA, which prohibits manufacturers from directly or indirectly advertising, marketing and promoting a drug for "off-label" usage, and instead requires that the manufacturer resubmit the drug to the FDA testing and approval process for the proposed new use and that the materials issued by the manufacturer relating to the proposed new use meet certain stringent requirements.

110. Defendants, as the manufacturer of Neurontin, directly and indirectly advertised, marketed and promoted Neurontin for the treatment of pain and encouraged that higher dosages than those tested be prescribed, even though defendants knew or should have known that there were not adequate tests and studies establishing and confirming that Neurontin was safe and effective for the treatment of bipolar disorder, and even though defendants knew or should have known that there were no adequate studies showing that Neurontin was safe when prescribed at dosages higher than those approved by the FDA.

111. At all times hereinafter mentioned, upon information and belief, defendants marketed and promoted Neurontin for the treatment of pain even though defendants knew or should have known that Neurontin caused many symptoms or related risk factors associated with suicidal behavior by persons suffering from pain.

112. At all times hereinafter mentioned, upon information and belief, defendants marketed and promoted Neurontin for the treatment of pain even though defendants knew or should have known that Neurontin had no effect in relieving or correcting the symptoms or causes

of pain.

113. Defendants' conduct in promoting "off-label" uses of Neurontin for treatment of pain constituted a wanton, callous and reckless disregard of the safety of the public and, in particular of persons suffering from pain.

114. In promoting "off-label" uses of Neurontin, and at higher dosages than approved by the FDA, including treatment of pain, defendants acted without regard to the potential danger and harm to persons for whom the drug was prescribed for the treatment of pain.

115. Defendants actively distributed, sold and placed Neurontin into the stream of commerce and directly and indirectly advertised, marketed and promoted Neurontin as being safe and effective for the treatment of pain and in dosages higher than those approved by the FDA, even though the only approved use of Neurontin at that time was as "adjunctive therapy" for the treatment of epilepsy and even though the FDA had specified a maximum recommended dosage.

116. Neurontin is not reasonably safe and effective for the treatment of persons suffering from bipolar disorder, and is not reasonably safe when consumed in higher dosages than those approved by the FDA, and defendants' conduct of illegally advertising, marketing and promoting Neurontin for this "off-label" uses was unlawful, deceptive and misleading and was violative of the FDCA.

117. By reason of defendants' conduct of directly and indirectly advertising, marketing and promoting Neurontin for the treatment of bipolar disorder in an unlawful manner, physicians commenced prescribing Neurontin to their patients diagnosed as suffering from bipolar disorder, frequently at dosages higher than those approved by the FDA.

118. Upon information and belief, defendant, WARNER-LAMBERT COMPANY LLC, was indicted in the United States District Court for the District of Massachusetts for violations of 21 U.S.C. §§ 331(a), 331(d), 333(a), 352(f)(1) and 355, and a copy of such criminal Information is annexed hereto as Exhibit "A" and incorporated into this complaint by reference.

119. Upon information and belief, on or about the 7th day of June, 2004, defendant, WARNER-LAMBERT COMPANY LLC, formally pled guilty to all charges contained in the Information.

120. The drug Neurontin was ineffective in the treatment of the causes and symptoms of plaintiffs' decedent's condition of pain and plaintiffs' decedent sustained injury and harm by reason of this reliance upon Neurontin to be effective in the treatment as prescribed by his physician of such pain condition.

121. That at all times hereinafter mentioned, plaintiffs' decedent was diagnosed by his physician as suffering from pain and was being treated by his physician for such condition.

122. That at all times hereinafter mentioned, upon information and belief, in reliance upon defendants' direct and indirect advertising, marketing and promoting of Neurontin as being safe and effective for the treatment of pain, plaintiffs' decedent's physician prescribed Neurontin to treat plaintiffs' decedent's pain.

123. That at all times hereinafter mentioned, plaintiffs' decedent purchased and consumed Neurontin, as recommended and prescribed by his physician and in the dosages prescribed, in an effort to control the effects of pain.

124. The drug Neurontin was not safe and effective for the treatment of plaintiffs' decedent's condition of pain, and plaintiffs' decedent sustained injury and harm by reason of his consumption of Neurontin as prescribed by his physician in an effort to treat his pain.

125. The drug Neurontin was ineffective in the treatment of the causes and symptoms of plaintiffs' decedent's condition of pain and plaintiffs' decedent sustained injury and harm by reason of this reliance upon Neurontin to be effective in the treatment as prescribed by his physician for such pain.

126. By reason of plaintiffs' decedent's consumption of Neurontin in a manner and at a dosage prescribed by his physician in an effort to treat his pain, on May 2, 2001, plaintiffs' decedent committed suicide.

127. The injuries and death sustained by plaintiffs' decedent were caused by or were contributed to by plaintiffs' decedent's consumption of Neurontin at a dosage prescribed by his physician for the treatment of pain in a manner consistent with the direct and indirect advertising, marketing and promoting of this drug for such "off-label" use by defendants.

FIRST CAUSE OF ACTION

Negligence

128. Plaintiffs repeat and reiterate the allegations previously set forth herein.

129. That at all times hereinafter mentioned, defendants were under a duty to exercise reasonable care in the design and development of Neurontin and, in particular, in the advertising, marketing and promoting of Neurontin, both directly and indirectly, to ensure that Neurontin was not used in the treatment of conditions such as pain for which it was not effective and to ensure that Neurontin was not used in a manner or to treat conditions where defendants knew or should have known that the user could sustain injuries and harm from the drug.

130. That defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that defendants, directly and indirectly, advertised, marketed and promoted Neurontin for the treatment of pain, even though Neurontin had not been scientifically determined to be safe for the treatment of pain and even though Neurontin was, in fact, not reasonably safe for the treatment of pain and furthermore, defendants failed to adequately warn of the risk of suicide or aggressive, self-destructive behavior of which defendants knew or should have known about.

131. That defendants were further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Neurontin even though such drug was not safe or effective for any purpose because it caused or influenced persons using the drug for any purpose to engage in self-destructive behavior including attempting to commit suicide and by failing to adequately warn the public of such risks.

132. Defendants have an ongoing duty of pharmacovigilance. As part of this duty, defendants are required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of their marketed drugs, including Neurontin. Defendants continually receive reports from their own clinical trials, practicing physicians, individual patients and regulatory authorities concerning adverse events that occur in patients taking Neurontin and

defendants' other marketed drugs. Furthermore, defendants continue to conduct clinical trials for their marketed drugs long after the drug is approved for use. Defendants have a continuing duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed drugs once that information becomes available to defendants, whether through defendants' clinical trials, other outside sources or pharmacovigilance activities. Specifically, when defendants learn, or should have learned, of new safety information associated with their marketed drugs, they have a duty to promptly disseminate that data to the public. Defendants also have a continuing duty to monitor epidemiology and pharmacovigilance data regarding their marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

133. Defendants were further negligent and breached this continuing duty of pharmacovigilance with respect to plaintiffs' decedent. Defendants, through clinical trials and other adverse event reports, learned that there was a serious problem of suicidality associated with Neurontin use and failed to inform doctors, regulatory agencies and the public of this risk. Defendants had the means and the resources to perform their pharmacovigilance duties for the entire time Neurontin has been on the market in the United States.

134. Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, inter alia, failing to report each adverse drug experience concerning Neurontin that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by defendants, failing to promptly investigate all adverse drug experiences concerning Neurontin that are the subject of these postmarketing 15-day Alert reports, failing to submit followup reports within 15 calendar days of receipt of new information or as requested by FDA, and, if additional information was not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information.

135. Defendants' failure to perform adequate pharmacovigilance and failure to comply with the postmarketing requirements of FDA regulations is evidence of defendants' negligence and constitutes negligence per se.

136 The death of plaintiffs' decedent was caused by or was contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including plaintiffs' decedent, on the part of defendants in the design, manufacture, distribution, advertising, marketing and promoting of Neurontin as being safe and effective in the treatment of pain and by inducing the public, including plaintiffs' decedent, to believe that Neurontin was effective in the treatment of the causes and symptoms of pain.

137 That at all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by defendants was a proximate cause of injuries sustained by plaintiffs' decedent.

138 That at all times hereinafter mentioned, plaintiffs' decedent did not contribute to plaintiffs' decedent's injuries by reason of any negligence or culpable conduct on plaintiffs' decedent's part.

139 That as a result of the aforesaid occurrence, the injuries sustained and the death of plaintiffs' decedent resulting therefrom, as aforesaid, the Next of Kin of plaintiffs' decedent suffered extensive monetary and pecuniary losses and other compensatory damages, and there was also incurred and paid out necessary medical, hospital, funeral and concomitant expenses.

140. That by reason of the facts and premises aforesaid, plaintiffs' decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiffs seek punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

SECOND CAUSE OF ACTION

Breach of Warranty

141. Plaintiffs repeat and reiterate the allegations previously set forth herein.

142. That at all times hereinafter mentioned, upon information and belief, defendants, by directly and indirectly advertising, marketing and promoting Neurontin for the treatment of pain and by placing this drug in the stream of commerce knowing that Neurontin would be

prescribed for the treatment of pain in reliance upon the representations of defendants, expressly warranted to all foreseeable users of this drug, including plaintiffs' decedent, that Neurontin was safe and effective for the treatment of pain.

143. That defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Neurontin to all foreseeable users, including plaintiffs' decedent, that Neurontin was safe and effective for the purposes for which it had been placed in the stream of commerce by defendants, including for the treatment of pain, and that Neurontin was reasonably safe, proper, merchantable and fit for the intended purpose, including for the treatment of pain.

144. That at all times hereinafter mentioned, plaintiffs' decedent relied upon the aforesaid express and implied warranties by defendants.

145. That at all times hereinafter mentioned, plaintiffs' decedent's use of Neurontin prior to and up to the time of the above-described incident was consistent with the purposes for which defendants directly and indirectly advertised, marketed and promoted Neurontin, and plaintiffs' decedent's use of Neurontin was reasonably contemplated, intended and foreseen by defendants at the time of the distribution and sale of Neurontin by defendants, and, therefore, plaintiffs' decedent's use of Neurontin was within the scope of the above-described express and implied warranties.

146. Defendants breached the aforesaid express and implied warranties because Neurontin was not safe and effective for the treatment of pain and because plaintiffs' decedent's use of Neurontin for the treatment of pain caused or contributed to the incident described herein.

147. Plaintiffs' decedent gave appropriate notice to defendants of the breach of the aforesaid express and implied warranties or such notice was otherwise excused.

148. That by reason of the facts and premises aforesaid, plaintiffs' decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiffs seek punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

THIRD CAUSE OF ACTION

Strict Liability

149. Plaintiffs repeat and reiterate the allegations previously set forth herein.

150. That at all times hereinafter mentioned, upon information and belief, defendants, by directly and indirectly advertising, marketing and promoting Neurontin for the treatment of pain and by placing this drug in the stream of commerce knowing that Neurontin would be prescribed for the treatment of pain in reliance upon the representations of defendants, expressly warranted to all foreseeable users of this drug, including plaintiffs' decedent, that Neurontin was safe and effective for the treatment of pain.

151. That defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Neurontin to all foreseeable users, including plaintiffs' decedent, that Neurontin was safe and effective for the purposes for which it had been placed in the stream of commerce by defendants, including for the treatment of pain, and that Neurontin was reasonably safe, proper, merchantable and fit for the intended purpose, including for the treatment of pain.

152. That at all times hereinafter mentioned, plaintiffs' decedent relied upon the aforesaid express and implied warranties by defendants.

153. That at all times hereinafter mentioned, plaintiffs' decedent's use of Neurontin prior to and up to the time of the above-described incident was consistent with the purposes for which defendants directly and indirectly advertised, marketed and promoted Neurontin, and plaintiffs' decedent's use of Neurontin was reasonably contemplated, intended and foreseen by defendants at the time of the distribution and sale of Neurontin by defendants, and, therefore, plaintiffs' decedent's use of Neurontin was within the scope of the above-described express and implied warranties.

154. Defendants breached the aforesaid express and implied warranties because Neurontin was not safe and effective for the treatment of pain and because plaintiffs' decedent's use of Neurontin for the treatment of pain caused or contributed to the incident described herein.

155. Plaintiffs' decedent gave appropriate notice to defendants of the breach of the

aforesaid express and implied warranties or such notice was otherwise excused.

156. That by reason of the facts and premises aforesaid, plaintiffs' decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiffs seek punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

FOURTH CAUSE OF ACTION

Fraud

157. Plaintiffs repeat and reiterate the allegations previously set forth herein.

158. Defendants materially misrepresented material facts concerning the safety and effectiveness of Neurontin in the treatment of pain.

159. Defendants' affirmative misrepresentations include but are not limited to the acts set forth in the following paragraphs.

160. In or about 1993, defendants submitted a new drug application (NDA) for approval of a drug called Neurontin (also known by the chemical name "Gabapentin"), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3(h)(4) and (5). In that application, defendants sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. On or about December 30, 1993, the FDA approved Neurontin for that specific use only. Because defendants had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than that approved use.

161. Commencing in at least June of 1995 and continuing through at least the date of this incident, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD), and migraine headaches, among other uses.

162. Defendants did not file a new NDA seeking FDA approval for any of these unapproved uses at any time prior to the date of this incident.

163. Defendants conducted evaluations of the market potential for certain of the unapproved uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

164. In or about the fall of 1995, defendants' Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including plans for conference calls on pain and a pain consultant meeting.

165. Certain defendants' annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies and tactics for increasing sales of the unapproved uses of the drug. The marketing plans budgeted for and funded these tactics.

166. Commencing in early 1995 and continuing at least through the date of this incident, defendants determined not to seek FDA approval for certain unapproved uses.

167. In or about April and May of 1995, defendants performed a marketing assessment of proposed psychiatric indications for Neurontin. In that marketing assessment, defendants forecast potential revenue from Neurontin for bipolar disorder and anxiety treatment under two scenarios: with and without FDA approval. Defendants' Neurontin Development Team and New Product Committee reviewed the potential uses and concluded that defendants would not seek approval to promote and sell the drug for these unapproved uses.

168. In or about July of 1995, defendants' assessment of Neurontin's market potential for neuropathic pain was distributed to defendants' Neurontin Development Team and to defendants' Vice President for marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to the FDA for approval.

169. One of the principal factors defendants considered in determining whether to seek

approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that defendants were developing. Defendants expected this new drug would be approved by the FDA not only for epilepsy but also for a variety of uses beyond Neurontin's approved use.

170. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in defendants' original NDA approval for Neurontin. If defendants sought and obtained approval for any of the unapproved uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those unapproved uses. Defendants were concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

171. Commencing about June of 1995 until at least the date of this incident, by certain conduct described in greater detail below, defendants promoted the sale and use of Neurontin for certain conditions other than the approved use.

172. In October 1995, a member of defendants' Epilepsy Disease Team circulated a memorandum to a group including other senior members of defendants' Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 of defendants' sales representatives for whom data was available in a two-month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

173. On or about July 10, 1996, defendants' sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

174. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales

representatives could present lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

175. Defendants employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following occasions, which are not all-inclusive, defendants' medical liaisons promoted Neurontin for unapproved uses:

(a) In or about June of 1996 defendants' sales representative requested that defendants' medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for unapproved uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of unapproved uses.

(e) After the presentation, defendants' Medical Director praised the event as "another great example of use of the medical liaisons" and an area business manager called it an "outstanding utilization of . . . one of the medical affairs liaisons."

176. Defendants organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida, on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to unapproved uses of Neurontin.

177. Defendants invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, defendants paid for accommodations and meals for the invited doctors and their spouse or guest, and paid an honorarium to each of the doctor attendees.

178. Among the presentations made to the physicians in attendance was one relating to

unapproved uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

179. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol and pain.

180. On or about May 8, 1996, following the Jupiter Beach conference, defendants circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations.

181. From August 1-5, 1996, defendants organized an "advisory board meeting," in Atlanta, Georgia, in conjunction with the 1996 Summer Olympics. Defendants expressly instructed several of the physician speakers to address some of the unapproved uses.

182. During that meeting, defendants hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. Defendants already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on defendants' behalf at prior meetings.

183. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

184. On or about March 1, 1996, defendants sponsored a teleconference moderated by defendants' employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

185. In or about May 1996, defendants' Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

186. Defendants hosted dozens of "consultants" meetings between late 1995 and 1997

in which the "consultants" received payments and gratuities as well as presentations on "off-label" Neurontin use designed to change the physicians' prescription writing habits. Such consultants' meetings included, but were not limited to the following:

Topic	Location	Dates
Mastering Epilepsy	La Costa Resort, CA	July 20-23, 1995
Mastering Epilepsy	Santa Fe, NM	Nov. 16-19, 1995
Neurontin Consultants Conference	Marco Island, FL	Feb. 2-4, 1996
Pediatric Epilepsy	Hutchinson Island, FL	Feb. 9-11, 1996
Mastering Epilepsy Science	Walt Disney World, FL	Feb. 22-25, 1996
Pediatric Epilepsy	Hutchinson Island, F	Mar. 8-10, 1996
Mastering Epilepsy	Ritz Carlton, Aspen, CO	Apr. 18-21, 1996
Affective Disorders in Psychiatry	Marco Island, FL	Apr. 20, 1996
Neurological Consultants (discussed previously)	Jupiter Beach, FL	Apr. 19-21, 1996
Affective Disorder Consultants Conference	Southern Pines, N	Apr. 27, 1996
Neuropathic Pain Conference	Palm Beach, FL	May 11, 1996
Regional Consultants Conference	Ritz Carlton, Boston, MA	May 10-11, 1996
Epilepsy Management Advisors Meeting	Sheraton Grande, Torrey Pines, La Jolla, CA	June 21-23, 1996
Epilepsy Management	Rancho Bernardo, CA	June 28-30, 1996
Use of Anti-Convulsants in Psychiatric Disorders	Short Hills, NJ	Oct. 18-19, 1996
Non-epileptic Uses of Neurontin	Longboat Key, FL	Nov. 6, 1996
Neurological Conditions Conference	Ritz Carlton, Atlanta, GA	Sep. 27-28, 1997

Other "consultants" meetings took place at Charleston, SC, Coconut Grove, FL, Naples, FL, Memphis, TN, Louisville, KY, Washington, DC, Aspen, CO, and other places. Hundreds, if not thousands, of physicians received kickbacks to attend these events.

187. Defendants rewarded doctors for their advocacy of Neurontin by paying them honoraria for lending their names to scientific articles which were actually prepared and written

by third parties retained by defendants. In 1996, defendants retained AMM/ADELPHI, Ltd. and Medical Education Systems, Inc., to prepare no less than twenty (20) articles for publication in various neurology and psychiatry journals. Most of these articles concerned "off-label" usage of Neurontin and were generated so that defendants could completely control the publications distributed pursuant to its "publications strategy." The content of these articles were actually written by non-physician technical writers retained by defendants and defendants had the right to control the content of all the articles. Defendants paid all expenses in connection with the creation of these publications.

188. Defendants also founded a speakers' bureau, another method of making large and numerous payments to physicians who recommended Neurontin for "off-label" uses, together with teleconferences, dinner meetings, consultants meetings, educational seminars, and other events.

189. Defendants utilized medical liaisons who were provided with new company slides that detailed methods to increase "off-label" use of Neurontin, including the following:

Reflex sympathetic dystrophy (RSD)
Peripheral neuropathy
Diabetic neuropathy
Trigeminal neuralgia
Post-herpetic neuralgia
Essential tremor
Restless leg syndrome (RLS)
Attention deficit disorder (ADD)
Periodic limb movement disorder
Migraine
Bipolar disorder
Amyotrophic lateral sclerosis (ALS/Lou Gehrig's Disease)
Drug or alcohol withdrawal seizures

190. The following enumerated misrepresentations, which are not intended to be all-

inclusive, relating to "off-label" usage of Neurontin, were routinely made to physicians with the knowledge and consent of marketing personnel of defendants:

a. *Bipolar Disorder.* Medical liaisons informed psychiatrists that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder indicated ninety percent (90%) response rate when Neurontin was started at 900 mg/day dosage and increased to a dosage of 4800 mg/day. No such results existed.

b. *Peripheral Neuropathy, Diabetic Neuropathy, and Other Pain Syndromes.* Medical liaisons stated that clinical trials demonstrated that Neurontin was highly effective in the treatment of various pain syndromes and that a ninety percent (90%) response rate in the treatment of pain was being reported. No such body of evidence existed. Defendants continued to claim that physicians should use Neurontin at substantially higher doses than indicated by the labeling. Indeed, although medical liaisons routinely claimed Neurontin to be effective as monotherapy, in 1997 the FDA refused to find Neurontin as a safe and effective monotherapy.

c. *Reflex Sympathetic Dystrophy ("RSD").* Medical liaisons informed physicians that extensive evidence demonstrated the efficacy of Neurontin in the treatment of RSD. The only such evidence that existed was anecdotal reports of nominal scientific value.

d. *Attention Deficit Disorder ("ADD").* Medical liaisons were instructed to inform pediatricians that Neurontin was effective for the treatment of ADD. No data, other than occasional anecdotal evidence, supported this claim.

e. *Restless Leg Syndrome ("RLS").* RLS was another condition where defendants' medical liaisons were trained to refer to a growing body of date relating to the condition, when no scientific date existed.

f. *Trigeminal Neuralgia.* Although medical liaisons represented that Neurontin could treat trigeminal neuralgia, again no scientific data supported this claim with the exception of occasional anecdotal reports. No data demonstrated that Neurontin was as effective as currently available pain killers, most of which were inexpensive.

g. *Post-Herpetic Neuralgia ("PHN").* Medical liaisons were trained to tell physicians that seventy-five percent (75%) to eighty percent (80%) of all PHN patients were successfully treated with Neurontin. Once again, no clinical trial data supported such a claim.

h. *Essential Tremor Periodic Limb Movement Disorder ("ETPLMD").* Medical liaisons were trained to allege that Neurontin was effective in the treatment of these conditions. No scientific data supported such claims with the exception of anecdotal reports of nominal scientific value.

i. *Migraine.* Claims that Neurontin was effective in the treatment of migraine headaches were made by the medical liaisons and were supposedly based on early results from clinical trials. Although pilot studies had been such suggested and undertaken, no early results of clinical trials existed to support these claims. Once again, any data relating to treatment of migraines was purely anecdotal and of nominal scientific value. Most of the case reports were either created or sponsored by defendants.

j. *Drug and Alcohol Withdrawal Seizures.* Medical liaisons suggested that Neurontin be used in the treatment of drug and alcohol withdrawals despite the lack of any data supporting Neurontin as an effective treatment for these conditions.

191. Defendants sponsored a 1998 study, which was scientifically valid, conducted at the Harvard Research Program, which concluded that patients receiving Neurontin did worse than those on sugar pills, but even though defendants were fully aware of these results from the tests which they sponsored, defendants did not publish the results until two years later after a substantial number of physicians had already been induced to prescribe Neurontin and a substantial number of patients had already been induced to take Neurontin.

192. At each of the presentations known to the plaintiff concerning Neurontin on pain, at least one of the presenters expressly stated or implied that Neurontin was effective for the treatment of pain. A representative statement was made by Dr. David Longmire, a participating physician, at the Jupiter Beach Consultants Meeting in April 1996 when he stated that Neurontin was effective for the treatment of pain. Dr. Longmire repeated that statement at a May 1996 Consultants Meeting at the Ritz Carlton in Boston. Another physician participant, Dr. Steven Schacter, made a similar statement at the May 1996 meeting when he stated that "pain specialists are finding that low dosages of Neurontin are effective." Comparable statements were made by

another physician participant, Dr. Bruce Nicholson, in April 1996 at the Jupiter Beach Consultants Meeting, in May 1996 at the Boston Ritz Carlton Consultants Meeting, and in June 1996 at a Philadelphia Consultants Meeting. Upon information and belief, similar statements were made at all events presented by defendants that discussed Neurontin's use for pain indications. These events include, but are not limited to the following events:

Topic	Date	Location
Neurontin Consultants Meeting	Apr. 19-21, 1996	Jupiter Beach, FL
Neurontin Consultants Meeting	May 3-4, 1996	Philadelphia, PA
Neurontin Consultants Meeting	May 10-11, 1996	Boston, MA
Advisory Board Meeting	Apr. 14-16, 2000	Grand Wailea Resort Hotel & Spa, Maui, HI
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
New Treatment Options for the Management of Pain: The Role of Anticonvulsants	Apr. 2000	Four Seasons Irving, TX
Advisory Board Meeting	May 26, 2000	Disney Yacht Club Orlando, FL
New Directions in the Understanding and Treatment of Pain	Mar. 24, 2001	Plaza Hotel New York, NY
New Directions in the Understanding and Treatment of Pain	Mar. 2-3, 2001	Hilton Novi Detroit, MI
New Directions in the Understanding and Treatment of Pain	May 4-5, 2001	Westin Galleria Houston, TX
New Directions in the Understanding and Treatment of Pain	Feb. 9-10, 2001	Harbor Court Hotel Baltimore, MD
New Directions in the Understanding and Treatment of Pain	Mar. 9-10, 2001	Fairmont Kansas City Kansas City, MO
New Directions in the Understanding and Treatment of Pain	May 11-12, 2001	Peabody Memphis Memphis, TN
New Directions in the Understanding and Treatment of Pain	Mar. 16-17, 2001	Fairmont San Francisco San Francisco, CA
Advisory Board Meeting	June 16-18, 2000	Westin Resort Hilton Head, SC

New Directions in the Understanding and Treatment of Pain	May 18-19, 2001	Sheraton Universal City Universal City, CA
New Directions in the Understanding and Treatment of Pain	May 18-19, 2001	Miami Biltmore Miami, FL
New Directions in the Understanding and Treatment of Pain	Mar. 23-24, 2001	Ritz Carlton New Orleans New Orleans, LA
New Directions in the Understanding and Treatment of Pain	Mar. 23-24, 2001	Sheraton Music City Nashville, TN
New Directions in the Understanding and Treatment of Pain	Mar. 30-31, 2001	Ritz Carlton St. Louis St. Louis, MO
New Directions in the Understanding and Treatment of Neuropathic Pain	Oct. 9-11, 1998	Madeira, Portugal

193. At events produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of restless leg syndrome or RSD. Events presented by defendants that discussed Neurontin's use as a treatment for restless leg syndrome or RSD include, but are not limited to, the following event:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

194. At events produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of bipolar disorder. Events presented by defendants that discussed Neurontin's use as a treatment for bipolar disorder include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess, Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire Beverly Hills, CA

Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place, New Orleans, LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrezia New York, NY
The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 1998	Barcelona, Spain

195. At events produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of social phobia. Events presented by defendants that discussed Neurontin's use as a treatment for social phobia include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess, Scottsdale, AZ
Merritt-Putnam Speakers Bureau Perspectives in the Current understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire Beverly Hills, CA
Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place, New Orleans, LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrezia New York, NY
The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 1998	Barcelona, Spain

196. Without favorable results from a well-designed panic disorder clinical trial that established Neurontin's efficacy for that condition, Parke-Davis had no reasonable scientific basis for claiming that Neurontin was effective in treating panic disorder. Nonetheless, at events

produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of panic disorder. Events presented by defendants that discussed Neurontin's use as a treatment for panic disorder include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess, Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorder	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire Beverly Hills,
Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place, New Orleans, LA
Merritt-Putnam Speakers Training Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrezia New York, NY

The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 1998	Barcelona, Spain

197. On September 13, 1996, Parke-Davis submitted a supplemental NDA to approve Neurontin as monotherapy for partial seizures. The FDA determined the application to be non-approvable on August 26, 1997, because of insufficiency of evidence of Neurontin's effectiveness. The FDA noted that Clinical Study 945-82 failed to yield evidence of effectiveness. Parke-Davis did not make public that its application for monotherapy had been denied. Representative events at which defendants continued to make presentations that Neurontin was effective for monotherapy without disclosing that the FDA had denied its application for a monotherapy indication include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Monotherapy Speakers Bureau Meeting	September 1997	La Quinta Resort Palm Springs, CA

198. Thereafter, pursuant to marketing strategies and tactics developed by Parke-Davis and defendants, defendants regularly presented programs in which physician participants touted Neurontin as being effective for the treatment of migraine. Events where such presentations were made include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Gabapentin in the Management of Migraine	May 25, 1996	Short Hills, NJ

199. Notwithstanding the FDA's refusal to increase the maximum approved dosage of Neurontin and its finding that no clinical evidence supported Neurontin's efficacy at dosages greater than 1800 mg per day, defendants presented numerous programs where physician participants asserted that Neurontin was effective and safe at dosages above 1800 mg. All such representations were false and misleading. Additionally, at these presentations the physician participants did not disclose the clinical trial evidence that demonstrated that there was no dose response above 1800 mg per day. Defendants' failure to provide this information was a violation

of defendants' duties to provide fair and balanced information, and made any prior representations about use of Neurontin at dosages greater than 1800 mg per day false and misleading. In addition to the events identified above, other events where these false and misleading statements were made include, but are not limited to, the following events:

Topic	Date	Location
Advisory Board Meeting on Neurontin	Feb. 4-6, 2000	Royal Sonesta New Orleans, LA
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire Beverly Hills, CA
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

200. On or about June 29, 2001, the FDA Division of Drug Marketing, Advertising and Communications (DDMAC) advised defendants that through routine monitoring and surveillance, the DDMAC has identified a slim jim (ID #NSJ5095A1) for Neurontin that is misleading and in violation of the FDCA and applicable regulations, in that this slim jim misleadingly claims improvement in quality of life (QOL) parameters based on the Neurontin Evaluation of Outcomes in Neurological Practice (NEON) study, that among other QOL parameters, the misleading presentation includes improvement in social limitations, memory difficulties, energy level, and work limitations, and that the NEON study is not considered to be substantial evidence for claims of QOL improvements because it is not a controlled study.

201. On or about July 1, 2002, the DDMAC advised defendants that through routine monitoring and surveillance, the DDMAC has identified a model (#NE 102254) for Neurontin (gabapentin) that is in violation of the FDCA and applicable regulations because it makes representations about Neurontin which are false or misleading, in that this suggestion of proof of the mechanism of action is false and contrary to the language in the approved product labeling that states "[t]he mechanism by which gabapentin [Neurontin] exerts its anticonvulsant action is unknown," and that, furthermore, the full presentation of the areas of the human brain accompanied by purported "Mechanism of Action" and the prominent display of the name "Neurontin" is misleading because it suggests that Neurontin is useful for a broader range of

central nervous system conditions than has been demonstrated by substantial evidence.

202. From July 1995 through at least August 5, 2002, defendants engaged in a marketing program to promote the use of Neurontin, and to induce physicians to prescribe Neurontin, for medical conditions for which the FDA had not approved Neurontin to be used (i.e., "unapproved" or "off-label" uses). That program included: (a) illegally promoting the sale and use of Neurontin for a variety of conditions other than the one condition for which its use was approved by the FDA and for which defendants had not performed the required FDA testing or established safety and efficacy, in violation of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 331, et seq.; (b) offering and paying illegal remuneration to doctors, either directly or through third parties, to induce them to promote and prescribe Neurontin for off-label uses, in violation of the federal Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b); and (c) making and/or disseminating false statements in presentations and marketing literature sales personnel provided to doctors concerning, among other things, the uses for which the FDA had approved Neurontin, the conditions for which the use of Neurontin was otherwise medically accepted and/or the existence of adequate evidence of the safety and efficacy for such use.

203. In order to avoid sanction and regulation by the FDA, defendants' off-label marketing scheme depended on their concealment of their involvement in off-label promotion of Neurontin, and to make it appear to the public that defendants did not have any hand in any discussions of off-label use. In addition, defendants performed off-label promotion in the semblance of legitimate consultants' meetings, continuing education seminars, journal articles and medical education events. Also, defendants' involvement was hidden because defendants hid their financial connections between the participating physicians and used the vendor participants as payment intermediaries. These activities and others described herein concealed defendants' off-label promotional activities, and plaintiff could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Much of the scheme to this day remains concealed by defendants.

204. In May 2003, the details of defendants' interactions with the other participants were disclosed through the filing by a former medical liaison, Dr. David Franklin, of previously

sealed materials in opposition to defendants' motion for summary judgment in the qui tam action. This "off-label" promotion scheme remained hidden until, the United States District Court for the District of Massachusetts Court unsealed Dr. Franklin's Amended Complaint in the qui tam case in April or May 2002.

205. In addition, defendants fraudulently concealed information and documents concerning the safety and efficacy of Neurontin, in particular, information and documents indicating that the ingestion of Neurontin for off-label uses and/or at high dosages, may cause suicidal ideations, gestures and acts.

206. Any applicable statutes of limitation have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs' decedent and other members of the public who were prescribed and ingested Neurontin for off-label uses have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part, and could not reasonably have discovered the fraudulent nature of defendants' conduct, and information and documents concerning the safety and efficacy of Neurontin, in particular, information and documents indicating that the ingestion of Neurontin for off-label uses and/or at high dosages, may cause suicidal ideations, gestures and acts. Accordingly, defendants are estopped from relying on any statute of limitations to defeat any of plaintiffs' claims.

207. Similarly, due to defendants' fraudulent concealment of the aforesaid documents and/or information, the scientific and/or medical community was not apprised of vital information concerning safety and efficacy of the drug Neurontin. Furthermore, due to the aforesaid allegations, plaintiffs may rely on the discovery rule in pursuit of this claim.

208. On information and belief, defendants' "off-label" promotion scheme continued after the filing of Dr. Franklin's whistleblower complaint and still continues. For example, through the third quarter of 2002, there were no published scientific studies to support Neurontin's use for a wide variety of diseases that it is being prescribed for including anxiety disorder, attention deficit disorder, bipolar disorder, cluster headache, depression, dosages in excess of 1800 mg per day and many other disorders that physicians are now prescribing

Neurontin for that are "off-label." Despite this lack of scientific evidence, Neurontin sales for these and other "off-label" uses have steadily increased, to the point that, according to an article published in the December 1, 2003 issue of Medical Marketing & Media, 90% of Neurontin sales are for "off-label" use. No other drug in the United States has such a high percentage of "off-label" use. The same article estimates that $1.8 billion worth of Neurontin has been sold for "off-label" uses. This increase in sales, and the repeated and increased prescription of Neurontin for "off-label" uses, without any supporting scientific studies that would be prompting such use, cannot be a random event and could not occur without continuing "off-label" promotion by defendants' sales force.

209. As a result of the activities described above, many of which continue to occur after Dr. Franklin filed his whistleblower suit, physicians were inundated with false information about Neurontin. As a result, they continue to prescribe Neurontin for "off-label" uses for which there is no reliable scientific support.

210. On information and belief, Pfizer has a company-wide practice of marketing "off-label" indications. "Off-label" marketing plans exist for Cox 2 inhibitors and, on information and belief, also exist for Neurontin.

211. This continuing course of conduct is evidenced in part by the staggering growth of Neurontin sales for "off-label" uses. Because there are no valid scientific studies supporting such use, a reasonable inference is that the use results from past and continuing promotional efforts by defendants. This clear and unavoidable conclusion follows from observations regarding the ongoing extent of prescriptions written for "off-label" Neurontin use.

212. First, from the perspective of overall Neurontin sales, "off-label" usage of Neurontin has actually increased during the years since 1999; in recent years, "off-label" prescriptions for Neurontin have exceeded 90% of all sales and, in some months, it appears that approved indication usage is negligible.

213. Second, although Neurontin is prescribed for scores of "off-label" indications, since 1999 the types of "off-label" usage continue to be weighted in the precise areas where defendants focused their illegal marketing efforts: bipolar disorder, peripheral neuropathy,

migraine, etc.

214. Third, these focus treatment areas of continuing unapproved usage are subject to very intense competition between therapeutic substitutes (other drugs or treatments). Indeed, because manufacturers' incremental cost for drugs in these areas is very small (e.g., only pennies to manufacture an additional pill), manufacturers compete aggressively for market share by spending huge amounts of money for marketing, promotional and sales activities. If any company were to simply pack its tent and discontinue programmatic promotional effort in any therapeutic arena, significant loss of overall sales within that diagnosis regime would certainly occur. For Neurontin, no such dip in overall sales, let alone any significant drop, has occurred.

215. Fourth, Pfizer, like most branded drug companies, monitors the relationship of its sales to its promotional efforts in very short timeframe; Pfizer would be concerned about a drop in sales within a certain therapeutic regime not after a yearly look-back, or even a quarterly look-back, but over just weeks. The persistent maintenance of high Neurontin sales within multiple, targeted areas for "off-label" promotion over a period of years defies the conclusion that any significant backing away on the marketing, sales or promotion of Neurontin to each of those approved therapeutic areas.

216. For example, sales of Neurontin for the treatment of bipolar disorder have steadily increased since its introduction. This increase is a direct result of defendants' sales representatives recommending to doctors its use for this purpose and their distribution of unapproved promotional materials. These promotional efforts did not stop in 1999, but continued thereafter. There are no valid scientific studies that support Neurontin's use for bipolar disorder. Dr. C. Seth Landefeld has submitted an expert opinion in the Franklin litigation that a review of Drugdex for Neurontin, as of the end of August 2002, reveals "no published scientific studies to support Neurontin's use for . . . bipolar disorder." As a result, tens of thousands of patients who need help and could use other drugs whose effectiveness has been established, were given and are being given Neurontin. These prescriptions for this purpose are still being written and as a direct result of defendants' pre-2000 illegal promotional activities and post-2000 illegal promotional activities.

217. Likewise, sales of Neurontin for pain, ALS, attention deficit disorder, depression and dosages in excess of 1800 mg per day, are also increasing without any scientific evidence supporting use of Neurontin for such indications. Again, as noted by Dr. Landefeld, as of the end of the third quarter of 2002 "there were no published scientific studies to support Neurontin's use for" any of these indications or in an increased dose.

218. Overall, "off-label" sales of Neurontin have steadily increased since 1998, and from 2000 to the present have consistently remained at 93% to 94% of all sales. Actual sales for approved uses have declined. Given the absence of scientific support for such uses, the genesis for those sales can only be past and continuing efforts by defendants to promote "off-label" use.

219. Defendants made additional fraudulent misrepresentations as to the safety and effectiveness of Neurontin, which are not detailed herein but will be determined in discovery.

220. Defendants affirmatively and fraudulently misrepresented that Neurontin was safe and effective in the treatment of bipolar disorder when, in actuality, Neurontin was ineffective in treating bipolar disorder and instead influenced users to engage in self-destructive behavior.

221. Defendants affirmatively and fraudulently misrepresented that Neurontin was safe for human consumption in general, when, in actuality, Neurontin influenced users to engage in self-destructive behavior.

222. Defendants knew that Neurontin was not safe and effective in the treatment of bipolar disorder and that Neurontin was not safe for human consumption in general because such drug influenced users to engage in self-destructive behavior.

223. Defendants knew that physicians, health care providers, and mental health care providers would justifiably rely upon defendants' misrepresentations in prescribing Neurontin in the treatment of bipolar disorder and in prescribing Neurontin for human consumption in general for the treatment of illnesses and medical and mental conditions and that the public, including persons such as plaintiffs' decedent, would justifiably rely upon defendants' misrepresentations in using Neurontin as prescribed by physicians, health care providers and mental health care providers in the treatment of bipolar disorder and for other prescribed uses.

224. Plaintiffs' decedent justifiably relied upon defendants' misrepresentations and,

accordingly, consumed Neurontin as prescribed by plaintiffs' decedent's physician in the treatment of pain.

225. By reason of plaintiffs' decedent's consumption of Neurontin in justifiable reliance upon defendants' fraudulent misrepresentations, plaintiffs' decedent sustained injuries and was caused to commit suicide.

226. That by reason of the facts and premises aforesaid, plaintiffs' decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiffs seek punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

FIFTH CAUSE OF ACTION

Violation of California Consumer Protection Act

227. Plaintiffs repeat and reiterate the allegations previously set forth herein.

228. Defendants knowingly and willfully engaged in unlawful, unfair and deceptive and acts and practices in the conduct of trade and commerce that adversely impacted the public interest, and disseminated information that were deceptive, misleading and false in a material way, in connection with the promotion and sale of Neurontin, in violation of California Business & Professional Code §§ 17200 et seq., and 17500 et seq. for the purpose of influencing and inducing physicians and medical providers to prescribe Neurontin, at excessively high dosages, for unapproved "off-label" uses, including treatment for pain, to patients/consumers such as plaintiffs' decedent, and knowingly took advantage of the inability of patients/consumers such as plaintiffs' decedent reasonably to protect their interests because of their physical and mental infirmities, and causing such patients/consumers to purchase, acquire and use Neurontin, at high dosages, for unapproved "off-label" uses, including treatment for pain, as prescribed by their physicians and medical providers.

229. By reason of defendants' unconscionable, unlawful, deceptive and unfair acts and practices, and dissemination of deceptive, misleading and false information, reasonable patients/consumers acting reasonably, such as plaintiffs' decedent, were caused to commit

suicide.

230. That by reason of the facts and premises aforesaid, plaintiffs' decedent's beneficiaries sustained actual damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiffs' seek punitive and exemplary damages against Defendant in an amount to be determined upon the trial of this matter, together with reasonable attorney's fees and costs.

SIXTH CAUSE OF ACTION

Survival Action

231. Plaintiffs repeat and reiterate the allegations previously set forth herein.

232. That at the time of the incident and during plaintiffs' decedent's consumption of Neurontin prior to and until the time of his death, plaintiffs' decedent suffered suicidal ideations and apprehension of death during a period of time leading up to the actual commission of suicide.

233. That for a period of time leading up to and at the time of the aforesaid suicide, plaintiffs' decedent lived and was suffering excruciating mental anguish, severe pain and suffering.

234. That by reason of the facts and premises aforesaid, plaintiffs' decedent's beneficiaries sustained damages recoverable pursuant to Cal. Code Civ. Proc. §§ 377.10 et. seq., in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiffs seek all damages available under applicable laws, including but not limited to, exemplary damages against defendants in an amount to be determined upon the trial of this matter.

235. Defendants are liable for all economic damages sustained by the estate of Alan Bennett.

236. Defendants are liable for all funeral expenses, medical special damages and any other out of pocket costs sustained by the plaintiffs.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for judgment against defendants as follows:

(1) General damages to be proven at time of trial;

(2) Special damages to be proven at time of trial;

(3) Attorneys' fees and costs, plus interest, as allowed by law;

(4) Punitive and exemplary damages; and

(4) Such other and further relief as the Court deems just and proper.

Plaintiffs hereby demand a trial by jury.

DATED: February 20, 2008

ROBINSON, CALCAGNI & ROBINSON INC.

Mark P. Robinson, Jr.

Mark P. Robinson, Jr., Esq.

Attorneys for Plaintiffs

Andrew G. Finkelstein, Esq.
Finkelstein & Partners, LLP
436 Robinson Avenue
Newburgh, NY 12550

Of Counsel for Plaintiffs

EXHIBIT "A"

FindLaw
WWW.FINDLAW.COM

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	Crim. No.
Plaintiff,	)	
v.	)	Violations: Title 21, United States Code Sections 331(a), 331(d), 352(f)(1), and 355(a)
WARNER-LAMBERT COMPANY LLC	)	
Defendant.	)	

INFORMATION

THE UNITED STATES ATTORNEY FOR THE DISTRICT OF MASSACHUSETTS CHARGES THAT:

GENERAL ALLEGATIONS

At all times material to this Information, unless otherwise alleged:

BACKGROUND

1. WARNER-LAMBERT COMPANY LLC (hereinafter "WARNER-LAMBERT"), was a corporation operating and existing under the laws of the State of Delaware. Its principal place of business was Morris Plains, New Jersey. WARNER-LAMBERT's Parke-Davis Division was engaged in, among other things, the development, manufacture, promotion, sale, and interstate distribution of prescription drugs intended for human use in the United States. WARNER-LAMBERT's pharmaceutical manufacturing facilities were located in Puerto Rico, from which it shipped products to all fifty states and the District of Columbia.

2. The Federal Food, Drug and Cosmetic Act ("FDCA"), among other things governs the lawful interstate distribution of drugs for human use. As codified at Title 21, United States Code, Sections 331 et seq., and specifically at § 355(b), the FDCA, and its implementing regulations, require that before a new drug may legally be distributed in interstate commerce, a sponsor of a new drug product must submit a New Drug Application ("NDA").

3. The FDCA required, at 21 U.S.C. § 355, that the NDA sponsor submit to the United States Food and Drug Administration ("FDA"), as part of an NDA, proposed labeling for the proposed intended uses for the drug which included, among other things, the conditions for therapeutic use. The NDA must also provide, to the satisfaction of FDA, data generated in

randomized and well-controlled clinical trials that demonstrates that the drug will be safe and effective when used in accordance with the proposed labeling.

4. The FDCA, at 21 U.S.C. § 355, prohibited the introduction into interstate commerce of any new drug, unless an approval of an NDA is effective. Only after the NDA, including the proposed labeling, was reviewed and approved by FDA, was the sponsor permitted by law to promote and market the drug, and only for the medical conditions of use specified in the approved labeling, for which use FDA had found sufficient evidence of safety and effectiveness. Uses unapproved by FDA, not included in the drug's approved labeling, are known as "unapproved uses" or "off-label uses."

5. The FDCA, and the regulations promulgated thereunder, required that in order to label or promote a drug for a use different than the conditions for use specified in the approved labeling, the sponsor had to file a new NDA, or amend the existing NDA, by, among other requirements, submitting the newly proposed indications for use and evidence, in the form of randomized and well-controlled clinical studies, sufficient to demonstrate that the drug would be safe and effective for the newly proposed therapeutic use or uses. Only upon approval of the new NDA could the sponsor promote the drug for the new intended use.

6. The FDCA, at 21 U.S.C. § 352(f)(1), provided that a drug was misbranded if, among other things, the labeling did not contain adequate directions for use. As the phrase is used in the FDCA, adequate directions for use cannot be written for medical indications or uses for which the drug had not been proven to be safe and effective through well-controlled clinical studies because that would be misleading under Section 352(a).

7. The FDCA, 21, U.S.C. §§ 331(a)(d), 333(a), and 355, prohibits the distribution in interstate commerce of an unapproved new drug or of a misbranded drug.

8. In or about 1993, WARNER-LAMBERT submitted an NDA for approval of a drug called Neurontin (also known by the chemical name gabapentin), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R.§ 310.3 (h)(4) and (5). In that application, WARNER-LAMBERT sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. On or about December 30, 1993, FDA approved Neurontin for that specific use only. This approved use for Neurontin will be referred to throughout this Information as the "Approved Use." Because WARNER-LAMBERT had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than the Approved Use. Further, Neurontin was not, pursuant to 21 U.S.C. § 355(i), exempt from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

9. As described in this Information, from at least June of 1995 through at least August 20, 1996, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD); and migraine headaches, among other uses.

These and other unapproved uses for Neurontin will be collectively referred to in this Information as the "Unapproved Uses."

10. WARNER-LAMBERT did not file a new NDA seeking FDA approval for any of these Unapproved Uses during the time period addressed in this Information. Of these Unapproved Uses, only post-herpetic neuralgia has ever received FDA approval, and that approval was applied for and received after the events described in this Information.

WARNER-LAMBERT'S STRATEGY FOR NEURONTIN

11. WARNER-LAMBERT conducted evaluations of the market potential for certain of the Unapproved Uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

12. In or about the fall of 1995, WARNER-LAMBERT's Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including conference calls on pain and a pain consultant meeting.

13. Certain of WARNER-LAMBERT's annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies, and tactics for increasing sales of the Unapproved Uses of the drug. The marketing plans budgeted for and funded these tactics.

14. From early 1995, on repeated occasions, WARNER-LAMBERT determined not to seek FDA approval for certain Unapproved Uses.

15. In or about April and May of 1995, WARNER-LAMBERT performed a Marketing Assessment of proposed psychiatric indications for Neurontin. In that Marketing Assessment, WARNER-LAMBERT forecast potential revenue from Neurontin for bipolar and anxiety treatment under two scenarios: with and without FDA approval. WARNER-LAMBERT's Neurontin Development Team and New Product Committee reviewed the potential psychiatric uses and concluded that the company would not seek approval to promote and sell the drug for these Unapproved Uses.

16. In or about July of 1995 WARNER-LAMBERT's assessment of Neurontin's market potential for neuropathic pain was distributed to its Neurontin Development Team and to a WARNER-LAMBERT Vice President for Marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to FDA for approval.

17. One of the principal factors WARNER-LAMBERT considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that WARNER-LAMBERT had been developing. The company expected this new drug would be approved by FDA not only for epilepsy but also for a variety of uses beyond Neurontin's Approved Use.

18. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in WARNER-LAMBERT's original NDA approval for Neurontin. If WARNER-LAMBERT sought and obtained approval for any of the

Unapproved Uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those Unapproved Uses. WARNER-LAMBERT was concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

WARNER-LAMBERT'S PROMOTION OF NEURONTIN FOR UNAPPROVED USES

19. From in or about June of 1995 through in or about August 20, 1996, by certain of the conduct described in greater detail below, WARNER-LAMBERT promoted the sale and use of Neurontin for certain conditions other than the Approved Use in Massachusetts and elsewhere:

OFF-LABEL PROMOTION THROUGH SALES REPRESENTATIVES

20. In October 1995, a member of WARNER-LAMBERT's Epilepsy Disease Team circulated a memorandum to a group including other senior members of WARNER-LAMBERT's Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 WARNER-LAMBERT sales representatives for whom data was available in a two month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

21. On or about July 10, 1996, a WARNER-LAMBERT sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

22. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales

representatives could do lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

OFF-LABEL PROMOTION THROUGH MEDICAL LIAISONS

23. WARNER-LAMBERT employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following occasion, a WARNER-LAMBERT medical liaison promoted Neurontin for Unapproved Uses:

(a) In or about June of 1996, a WARNER-LAMBERT sales representative requested that a WARNER-LAMBERT medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for Unapproved Uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of Unapproved Uses.

(e) After the presentation, a WARNER-LAMBERT Medical Director praised the event as "another great example of use of the medical liaisons" and an Area Business Manager called it an "outstanding utilization of . . . one of the medical affairs liaisons."

24. In or about May 1996, a WARNER-LAMBERT Medical Director based in the Northeast CBU sent a voicemail message to the Medical Liaisons in the Northeast CBU in which he stated:

> What we'd like you to do is, any time you're called out just make sure that your main focus out of what you're doing is on Neurontin . . . When we get out there, we want to kick some ass, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do.

One or more Medical Liaisons in the Northeast CBU interpreted this statement to mean that he or she should promote Neurontin for Unapproved Uses and thereafter, in or about May and June 1996, promoted Neurontin for neuropathic pain, an unapproved use.

OFF-LABEL PROMOTION THROUGH CONSULTANTS' MEETINGS AND ADVISORY BOARDS

25. WARNER-LAMBERT organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to Unapproved Uses of Neurontin.

26. WARNER-LAMBERT invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, WARNER-LAMBERT paid for accommodations and meals for the invited doctors and

their spouse or guest, and paid an honorarium to each of the doctor attendees. Doctors who acted as faculty were paid between $1,500 and $2,000.

27. Among the presentations made to the physicians in attendance was one relating to Unapproved Uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

28. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol, and pain.

29. On or about May 8, 1996, following the Jupiter Beach conference, WARNER-LAMBERT circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations. WARNER-LAMBERT told its employees that: "[t]he meeting was a great success and the participants were delivered a hard-hitting message about Neurontin." WARNER-LAMBERT distributed to these employees a form entitled "Jupiter Beach Trending Worksheet" which was intended to be used to gauge the effect of the meeting on the prescribing by doctors who attended the Jupiter Beach meeting.

30. From August 1-5, 1996, WARNER-LAMBERT organized an "advisory board meeting," in Atlanta, Georgia in conjunction with the 1996 Summer Olympics. WARNER-LAMBERT expressly instructed several of the physician speakers to address some of the Unapproved Uses.

31. During that meeting, WARNER-LAMBERT hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. The company had already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on WARNER-LAMBERT's behalf at prior meetings.

32. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

OFF-LABEL PROMOTION THROUGH TELECONFERENCES

33. In or about January, 1996, a WARNER-LAMBERT Vice President of the Southeast Customer Business Unit sent a memorandum to WARNER-LAMBERT sales representatives listing certain goals, including: "Utilize the Medical Liaison Group to target the Neurontin, Pain & Psychiatric market. Objective to conduct twice weekly Pain Teleconferences moderated by key Neuro Consultants. Goals 250 Physicians Participants quarterly."

34. On or about March 1, 1996, WARNER-LAMBERT sponsored such a teleconference moderated by a WARNER-LAMBERT employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

35. On or about March 28, 1996, a WARNER-LAMBERT Medical Director in the Northcentral Customer Business Unit sent a memorandum to WARNER-LAMBERT Medical Liaisons in that unit instructing them to hold a series of teleconferences with doctors to provide clinical updates on Neurontin, including monotherapy epilepsy data and non-epilepsy use data entitled "Neurontin, A Clinical Update."

36. In or about May, 1996, a WARNER-LAMBERT Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

COUNT ONE: 21 U.S.C. §§ 331(d), 333(a)(2) & 355(a)

(Distribution of an Unapproved New Drug)

37. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

38. Beginning as early as in or about April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts, and elsewhere,

WARNER-LAMBERT,

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses. No approval, pursuant to 21 U.S.C. § 355, was in effect with respect to Neurontin for use in these conditions.

All in violation of 21 U.S.C. §§ 331(d), 333(a)(2), and 355(a).

COUNT TWO: 21 U.S.C. §§ 331(a), 333(a)(2) & 352(f)(1)

(Distribution of a Misbranded Drug: Inadequate Directions for Use)

39. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

40. Beginning as early as April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts and elsewhere,

WARNER-LAMBERT,

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses, and which was misbranded within the meaning of 21 U.S.C. § 352(a), in that Neurontin's labeling lacked adequate directions for such uses.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(f)(1).

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

THOMAS E. KANWIT
ASSISTANT U.S. ATTORNEY

May 13, 2004

UNITED STATES
DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
SAN DIEGO DIVISION

# 147945 - SH
*** * C O P Y * ***
February 21, 2008
16:16:36

Civ Fil Non-Pris
USAO #.: 08CV0341
Judge..: LARRY A BURNS
Amount.: $350.00 CK
Check#.: BC009767

Total-> $350.00

FROM: BENNETT ET AL V. PFIZER

OJS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

MARILYN BENNETT, SCOTT BENNETT and CHAD BENNETT, all individually and as successors in interest to the Estate of ALAN BENNETT, Deceased,

(b) County of Residence of First Listed Plaintiff: San Diego
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Mark P. Robinson, Jr., Esq.
Robinson, Calcagni & Robinson Inc.
620 Newport Center Drive, 7th Floor
Newport Beach, CA 92660
Telephone (949) 720-1288

DEFENDANTS

PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner Lambert Company LLC, WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC

FILED
08 FEB 21 PM 4:12
CLERK U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
BY DEPUTY

County of Residence of First Listed Defendant: NEW YORK
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

'08 CV 0341 LAB LSP

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
- 3 Federal Question (U.S. Government Not a Party)
- 2 U.S. Government Defendant
- X 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant) (For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	1	1	Incorporated *or* Principal Place of Business In This State	4	4
Citizen of Another State	x 2	2	Incorporated *and* Principal Place of Business In Another State	5	x 5
Citizen or Subject of a Foreign Country	3	3	Foreign Nation	6	6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
110 Insurance; 120 Marine; 130 Miller Act; 140 Negotiable Instrument; 150 Recovery of Overpayment & Enforcement of Judgment; 151 Medicare Act; 152 Recovery of Defaulted Student Loans (Excl. Veterans); 153 Recovery of Overpayment of Veteran's Benefits; 160 Stockholders' Suits; 190 Other Contract; 195 Contract Product Liability

TORTS
PERSONAL INJURY: 310 Airplane; 315 Airplane Product Liability; 320 Assault, Libel & Slander; 330 Federal Employers' Liability; 340 Marine; 345 Marine Product Liability; 350 Motor Vehicle; 355 Motor Vehicle Product Liability; 360 Other Personal Injury
PERSONAL INJURY: 362 Personal Injury—Med. Malpractice; x 365 Personal Injury — Product Liability; 368 Asbestos Personal Injury Product Liability
PERSONAL PROPERTY: 370 Other Fraud; 371 Truth in Lending; 380 Other Personal Property Damage; 385 Property Damage Product Liability

FORFEITURE/PENALTY
610 Agriculture; 620 Other Food & Drug; 625 Drug Related Seizure of Property 21 USC 881; 630 Liquor Laws; 640 R.R. & Truck; 650 Airline Regs.; 660 Occupational Safety/Health; 690 Other

LABOR
710 Fair Labor Standards Act; 720 Labor/Mgmt Relations; 730 Labor/Mgmt Reporting & Disclosure Act; 740 Railway Labor Act; 790 Other Labor Litigation; 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
422 Appeal 28 USC 158; 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
820 Copyrights; 830 Patent; 840 Trademark

SOCIAL SECURITY
861 HIA (1395ff); 862 Black Lung (923); 863 DIWC/DIWW (405(g)); 864 SSID Title XVI; 865 RSI (405(g))

FEDERAL TAX SUITS
870 Taxes (U.S. Plaintiff or Defendant); 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
400 State Reapportionment; 410 Antitrust; 430 Banks and Banking; 450 Commerce/ICC Rates/etc.; 460 Deportation; 470 Racketeer Influenced and Corrupt Organizations; 480 Consumer Credit; 490 Cable/Sat TV; 810 Selective Service; 850 Securities/Commodities Exchange; 875 Customer Challenge 12 USC 3410; 890 Other Statutory Actions; 891 Agricultural Acts; 892 Economic Stabilization Act; 893 Environmental Matters; 894 Energy Allocation Act; 895 Freedom of Information Act; 900 Appeal of Fee Determination Under Equal Access to Justice; 950 Constitutionality of State Statutes

REAL PROPERTY
210 Land Condemnation; 220 Foreclosure; 230 Rent Lease & Ejectment; 240 Torts to Land; 245 Tort Product Liability; 290 All Other Real Property

CIVIL RIGHTS
441 Voting; 442 Employment; 443 Housing/Accommodations; 444 Welfare; 445 Amer. w/ Disabilities Employment; 446 Amer. w/ Disabilities - Other; 440 Other Civil Rights

PRISONER PETITIONS
510 Motions to Vacate Sentence; Habeas Corpus: 530 General; 535 Death Penalty; 540 Mandamus & Other; 550 Civil Rights; 555 Prison Condition

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

x 1 Original Proceeding; 2 Removed from State Court; 3 Remanded from Appellate Court; 4 Reinstated or Reopened; 5 Transferred from another district (specify); 6 Multidistrict Litigation; 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
(Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 USC Sec. 1332 based on diversity
Brief description of cause: Civil action to recover damages for personal injuries caused by the prescription drug Neurontin

VII. REQUESTED IN COMPLAINT:
CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND $ Excess of $75,000
CHECK YES only if demanded in complaint:
JURY DEMAND: x Yes No

VIII. RELATED CASE(S) IF ANY (See instructions):
MDL 1629 IN re Neurontin Marketing and Sales Practices Litigation
JUDGE Hon. Patti B. Saris DOCKET NUMBER 1:04-10981 PBS

DATE February 20 2008
SIGNATURE OF ATTORNEY OF RECORD: Mark P. Robinson, Jr.

FOR OFFICE USE ONLY

RECEIPT # 147945 AMOUNT $350 APPLYING IFP JUDGE MA. JUDGE

LR Su 2/21/08